OraSure Technologies Receives BARDA Funding for Coronavirus Antibody ELISA Using Oral Fluid Samples

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BETHLEHEM, Pa., June 10, 2020 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests, specimen collection devices and microbiome laboratory and analytical services, today announced it has been awarded a $629,217 contract from the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, to develop an Enzyme-Linked Immunosorbent Assay (ELISA) for the detection of human anti-SARS-CoV-2 antibodies in oral fluid specimens. Currently, there are no oral fluid-based COVID antibody tests available with automated assays.

This support from BARDA will help OraSure complete development and file for FDA Emergency Use Authorization (EUA), which would allow the laboratory-based microplate antibody test for oral fluid samples to enter into the U.S. market. This is the second COVID-related test for which the company has received BARDA funding. The first, a rapid, antigen in-home oral fluid self-test, was announced in April.

“The coronavirus pandemic is complicated and fast moving. It will take a variety of tests to get it under control,” said OraSure President and Chief Executive Officer Stephen S. Tang, Ph.D. “Understanding who is contagious and who has potentially protective antibodies will be crucial as the country continues reopening the economy and returning to everyday life. We believe that the combination of the OraSure antibody and antigen tests along with our sample collection capabilities, can give people insight into their COVID-19 status across the infection spectrum. We are proud to bring our proven expertise with oral fluid collection and testing to this global pandemic.”

This oral fluid ELISA is expected to increase laboratory COVID-19 antibody testing capacity and could play a vital role in detecting coronavirus antibodies which can be detected within one to three weeks after the onset of symptoms. Such tests could help identify people who had past COVID-19 infections, even without symptoms, potentially allowing them to safely return to work or other activities if data show antibody development with past infection translates to future immunity. In addition, this test could help meet an urgent need to screen the population, especially health care workers, for past asymptomatic infection and potential immunity against COVID-19.

With this test, human antibodies found in oral fluid would be collected via a wand and pad and eluted into the OraSure® oral fluid specimen collection device buffer for storage and transport, and later dispensed onto the ELISA microplate for testing in a laboratory. The assay, in conjunction with the collection device, would be utilized under FDA's Emergency Use Authorization (EUA).

Under the initial EUA, if obtained, the collection device would be available for specimen collection in a physician's office, a lab or a testing facility.

The EUA subsequently could be amended to permit an in-home or self-collection option. Being able to collect samples at home would promote social distancing and minimize healthcare workers' exposure to patients who potentially are infected.

Oral fluid testing also provides an easier and pain-free sample collection method as compared to nasopharyngeal or oropharyngeal samples or serology antibody tests which require a blood draw.

Assuming product development and clinical testing are successful, OraSure is targeting initial product sales this summer with Emergency Use Authorization (EUA) following shortly thereafter.

In April, the company announced the first COVID-19 test in development with funding from BARDA. That test is a pan-SARS-coronavirus rapid antigen in-home self-test that uses oral fluid samples and provides results in-home or at the point of collection. OraSure is also working with laboratories and researchers to demonstrate the effectiveness of certain of its molecular sample collection technologies for coronavirus testing. To date, three of its sample collection devices have been incorporated into assays receiving FDA EUA, illustrating the versatility of its products for COVID-19 detection. Strong data on the usability of OraSure’s molecular collection products support this usage of its products for COVID-19 related applications.

This project has been funded in whole or in part with federal funds from the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50120C00122.

About OraSure Technologies

OraSure Technologies empowers the global community to improve health and wellness by providing access to accurate, essential information. Together with its wholly-owned subsidiaries, DNA Genotek, Diversigen CoreBiome (now operating under the Diversigen brand) and Novosanis, OraSure provides its customers with end-to-end solutions that encompass tools, services and diagnostics. The OraSure family of companies is a leader in the development, manufacture, and distribution of rapid diagnostic tests, sample collection and stabilization devices, and molecular services solutions designed to discover and detect critical medical conditions. OraSure’s portfolio of products is sold globally to clinical laboratories, hospitals, physician’s offices, clinics, public health and community-based organizations, research institutions, government agencies, pharma, commercial entities and direct to consumers. For more information on OraSure Technologies, please visit www.orasure.com.

Important Information

This press release contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to successfully manage and integrate acquisitions of other companies in a manner that complements or leverages our existing business, or otherwise expands or enhances our portfolio of

products and our end-to-end service offerings, and the diversion of management's attention from our ongoing business and regular business responsibilities to effect such integration; the expected economic benefits of acquisitions (and increased returns for our stockholders), including that the anticipated synergies, revenue enhancement strategies and other benefits from the acquisitions may not be fully realized or may take longer to realize than expected and our actual integration costs may exceed our estimates; impact of increased or different risks arising from the acquisition of companies located in foreign countries; ability to market and sell products, whether through our internal, direct sales force or third parties; impact of significant customer concentration in the genomics business; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration ("FDA") or other regulators; the impact of the novel coronavirus ("COVID-19") pandemic on our business and our ability to successfully develop new products, validate the expanded use of existing collector products and commercialize such products for COVID-19 testing; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention ("CDC") or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; impact of contracting with the U.S. government; impact of negative economic conditions; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors that could affect our results are discussed more fully in our SEC filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2019, Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.

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